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10/786,171	02/26/2004	Robert Frost	029082.53185US	9141

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EXAMINER
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JOYNER, KEVIN

ART UNIT	PAPER NUMBER
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1744

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08/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/786,171

Applicant(s)

FROST, ROBERT

Examiner

Kevin C. Joyner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4, 6, 11, 12, 14, 16, 20-21, 26, 28-29, 31, 32, 34, 36-39, 41-45, and 47-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 7-10, 13, 15, 17-19, 22-25, 27, 30, 33, 35, 40 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/16/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I in the reply filed on July 11, 2007 is acknowledged. The traversal is on the ground(s) that both of the groups are directed to the core of the invention comprising a process in which a gas permeable packaging is sterilized on its outside without significant amounts of hydrogen peroxide steam being introduced in the interior of the packaging. This is not found persuasive because as disclosed in the previous Office Action, Group I and Group II are related as a Combination/Subcombination where the combination does not require the particulars of the subcombination. In accordance with MPEP 806.05(c), inventions of this relationship are **distinct** if the combination does not require the particulars of the subcombination. As previously stated, the combination does not require the transport containers to be released from their additional packaging. Thus, the inventions are distinct, and are considered as such.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Objections*

2. Claims 22 and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s)

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in proper dependent form, or rewrite the claim(s) in independent form. Appropriate action is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 15, 24, 33, 40, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 24 recites the limitation "the time span" in line 1. There is insufficient antecedent basis for this limitation in the claim. The Office suggests the Applicant to amend the claim to depend from claim 23.

6. Claim 5 recites the limitation "the transport container" in line 3. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 15 recites the limitation "the transport container" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 33 recites the limitation "the transport container" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 40 recites the limitation "the transport container" in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 46 recites the limitation "the transport container" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 3, 7-9, 13, 17-19, 22-25, 27, 30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Prior Art Admission in view of Frost et al. (U.S. Publication No. 2002/0054826).

The Applicant discloses that a process for operating a packaging transport system, comprising the steps of: sterilizing objects packed in at least one layer of packaging which is bacteria-impermeable and gas-permeable; placing the sterilized objects packed in at least one layer of the at least one layer of packaging into a sterilization chamber in the form of a transfer lock; and transferring the sterilized objects and packaging into a sterile clean room is known as prior art knowledge (paragraphs 4-9 of the specification). The Applicant does not appear to disclose that the sterilization chamber in the form of a transfer lock is an evacuable sterilization chamber, and that the process further comprises pre-evacuating the sterilization chamber; applying abruptly a vapor mix consisting of water steam and hydrogen peroxide steam as a condensate layer onto the outer side of the packaging; and re-evacuating the sterilization chamber to remove the condensate layer and the uncondensed vapor mix before either the vapor mix or the condensate layer penetrates through the packaging to

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the objects at an inadmissible level. Frost discloses a method of operating a transport system comprising (paragraphs 30-31); pre-evacuating the sterilization chamber (paragraph 32); applying abruptly a vapor mix consisting of water steam and hydrogen peroxide steam as a condensate layer onto the outer side of an object (paragraphs 21-22 and 33); and re-evacuating the sterilization chamber to remove the condensate layer and the uncondensed vapor mix before either the vapor mix or the condensate layer penetrates through the objects at an inadmissible level (paragraph 33) in order to provide an expedient process for the sterilization of the object. Since the method of Frost comprises a contact time of less than three seconds, then the vapor mix or the condensate layer does not penetrate through the an object at an inadmissible level. More specifically, the Applicant discloses that it is known to sterilize objects, package them, and transport them to a clean room. The Applicant continues to disclose that it is known that the packages may become contaminated when transporting them to the clean room and that processes are known to sterilize, in a transfer lock, only the outer portion of the packages, so that the objects inside the package are in no way impaired (paragraph 9). Frost discloses a method of sterilizing an object by abruptly applying a sterilizing vapor comprising the steps as set forth above in order to provide an extremely fast and efficient sterilization process. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of the Applicant's Admitted Prior Art to utilize the sterilization method of Frost comprising an evacuable sterilization chamber with the process steps of pre-evacuating the sterilization chamber; applying abruptly a vapor mix consisting of water steam and

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hydrogen peroxide steam as a condensate layer onto the outer side of the packaging; and re-evacuating the sterilization chamber to remove the condensate layer and the uncondensed vapor mix before either the vapor mix or the condensate layer penetrates through the packaging to the objects at an inadmissible level in order to provide an extremely fast and efficient sterilization process to the packages.

Regarding claim 3, Frost also discloses that the pressure difference between a pressure of the vapor mix and a pressure in the evacuated sterilization chamber forces the vapor mix to be fed into the sterilization chamber without the use of carrier gas. Regarding claims 7-10, Frost also discloses that the condensate layer is removed from the sterilization chamber immediately after the vapor mix has been fed into the sterilization chamber (paragraph 33) and that the removal of the condensate layer by means of evacuation of the sterilization chamber takes place at a pressure below 1 mb (paragraph 18). Regarding claim 13, Frost discloses that the chamber is filled with a sterile air after the condensate layer has been removed (paragraph 33). More specifically, sterile air is known in the art of sterilization to be a sterilizing gas. Concerning claim 30, Frost discloses that the pre-evacuation, vapor mix application, and re-evacuation steps are repeated at least once (paragraph 25). Regarding claim 35, the reference also discloses that the removal of the condensate layer takes place at a pressure below the steam pressure of a water and hydrogen peroxide solution corresponding to the temperature in the sterilization chamber during sterilization (paragraph 17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of the Applicant's Admitted Prior Art to

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utilize the sterilization method of Frost comprising the steps as disclosed above in order to provide an extremely fast and efficient sterilization process to the packages.

Claims 17-19, 22, 23-25, and 27 further disclose that the time span of a maximum of 2 seconds is provided from the beginning of the flowing in of the vapor mixture to the beginning of the re-evacuation to provide a level of hydrogen peroxide residue below 0.5 ppm to a great extent. Frost continues to disclose that the vapor mixture flows to the sterilization chamber abruptly wherein the mixture condensates in the shortest time possible on all the surfaces exposed thereto (paragraph 21), and that the contact time of the condensation fluid is less than three seconds (paragraph 33). Therefore, it would have been well within the purview of one of ordinary skill in the art of the time of the invention to optimize the time span of a maximum of 2 seconds being provided from the beginning of the flowing in of the vapor mixture to the beginning of the re-evacuation, which would result in an hydrogen peroxide residue level below 0.5 ppm to a great extent in order to maximize the sterilization process of the Applicant's Admitted Prior Art in view of Frost. Only the expected results would be attained.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Prior Art Admission in view of Frost et al. (U.S. Publication No. 2002/0054826) as applied to claims 1, 3, 7-9, 13, 17-19, 22-25, 27, 30, and 35 above, and further in view of Zimmerman (U.S. Patent No. 3,117,441).

14. The Applicant's Admitted Prior Art in view of Frost is relied upon as set forth above. The Applicant's Admitted Prior Art in view of Frost does not appear to disclose that the speed of the pre-evacuation is adapted to the flow resistance of the gas-

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permeable cover of the transport container to ensure a gas pressure within the covered transport container remains above a pressure in the sterilization chamber. Zimmerman discloses a process for operating a packaging transport system (Figure 1), wherein the speed of the pre-evacuation is adapted to the flow resistance of the gas-permeable cover of the transport container in order to ensure that a gas pressure within the covered transport container remains above a pressure in a chamber (column 6, lines 1-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Applicant's Admitted Prior Art in view of Frost to adapt the speed of the pre-evacuation with the flow resistance of the gas-permeable cover of the transport container in order to ensure a gas pressure within the covered transport container remains above a pressure in the sterilization chamber as exemplified by Zimmerman.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Prior Art Admission in view of Frost et al. (U.S. Publication No. 2002/0054826) as applied to claims 1, 3, 7-9, 13, 17-19, 22-25, 27, 30, and 35 above, and further in view of Dodrill (U.S. Patent No. 5,283,033).

16. The Applicant's Admitted Prior Art in view of Frost is relied upon as set forth above, wherein the method discloses a condensate layer being applied to a package. However, the Applicant's Admitted Prior Art in view of Frost does not appear to disclose that the layer is applied before an inner pressure of the packaging has reached a pressure of the sterilization chamber. Dodrill discloses a method for operating a packaging transport system (column 5, lines 12-25), wherein packages are sterilized in

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a chamber with the pressures of the package and the chamber being closely monitored (column 5, lines 25-55). The method continues to disclose that the sterilization process takes place in a manner wherein the pressure inside of the packages remains above the pressure in the chamber (column 6, lines 45-50), and thus the sterilization takes place before the inner pressure of the packaging has reached a pressure of the sterilization chamber in order to prevent the packaging from collapsing at a vulnerable point.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the Applicant's Admitted Prior Art in view of Frost to apply the condensate layer before an inner pressure of the packaging has reached a pressure of the sterilization chamber in order to prevent the packaging from collapsing at a vulnerable point as exemplified by Dodrill.

17. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Prior Art Admission in view of Frost et al. (U.S. Publication No. 2002/0054826) as applied to claims 1, 3, 7-9, 13, 17-19, 22-25, 27, 30, and 35 above, and further in view of Lin (U.S. Patent No. 6,685,895).

18. The Applicant's Admitted Prior Art in view of Frost is relied upon as set forth above. The Applicant's Admitted Prior Art in view of Frost does not appear to disclose that the supporting surfaces of the transport container adapted for use with a holding device or a transport device, and the support surfaces are altered before the pre-evacuation, vapor mix application and re-evacuation steps are repeated. Lin discloses a process for sterilizing objects in a sterilization chamber that comprises two cycles of sterilization, wherein supporting surfaces of the object are adapted for use with holding

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the object and the support surfaces are altered before the second cycle takes place in order to ensure that the entire object is sterilized. More specifically, the objects are supported by a surface at a first position during a first sterilization cycle. The supporting surface is then moved from the first position to a second position so that the first position is sterilized during the second cycle (column 3, lines 35-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of the Applicant's Admitted Prior Art in view of Frost to comprise supporting surfaces of the transport container adapted for use with a holding device or a transport device, and the support surfaces are altered before the pre-evacuation, vapor mix application and re-evacuation steps are repeated in order to ensure that the entire device is sterilized as exemplified by Lin.

19. Claims 40 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Prior Art Admission in view of Frost et al. (U.S. Publication No. 2002/0054826) as applied to claims 1, 3, 7-9, 13, 17-19, 22-25, 27, 30, and 35 above, and further in view of Croce et al. (U.S. Patent No. 4,771,630).

20. The Applicant's Admitted Prior Art in view of Frost is relied upon as set forth above. The Applicant's Admitted Prior Art in view of Frost does not appear to disclose that the container leakage is detected by the analysis of sterilization chamber pressure, or that the transport container leakage occurring before the transport containers are guided into the sterilization chamber is detected by monitoring the curvature of the cover. Croce discloses a method of analysis for container leakage in columns 1 and 2. The reference continues to disclose that the container leakage is detected by the

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analysis of a chamber pressure in order to determine if the objects inside the container have been compromised by outside air (column 4, lines 25-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the Applicant's Prior Art Admission in view of Frost to detect container leakage by an analysis of the chamber pressure in order to determine if the objects inside the container have been compromised by outside air as exemplified by Croce. Regarding claim 46, Croce continues to disclose that the packages are sealed and provided with an air space between the outside package and the object being packaged, wherein the air space creates a curve on the package and can be visually inspected for package leaks (column 1, lines 42-65). As such, Croce provides a teaching for checking the packages for leaks by monitoring the curvature of the cover that is completed before adding it to a chamber. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the Applicant's Admitted Prior Art in view of Frost to detect container leakage before transporting the container into the sterilization chamber by monitoring the curvature of the cover in order to ensure that the containers are properly sealed before entering the chamber as exemplified by Croce.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCJ

  
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